Wisconsin's SeniorCare Pharmaceutical Benefit for Low-Income Seniors
CMS Section 1115 Waiver Project, 2019 Renewal

Evaluation Design Report

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The preparation of this design report benefited from regular consultation with staff of the Wisconsin Department of Health Services, including Tiffany Reilly and Susan Siebert

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ABBREVIATIONS & GLOSSARY OF TERMS

CCW	Chronic Conditions Data Warehouse
CMS	Centers for Medicare and Medicaid Services
CMR/A	Comprehensive Medication Review and Assessment
EBD	Elderly, Blind, and Disabled
FDA	Food and Drug Administration
FPL	Federal Poverty Level
GLM	Generalized Linear Model
LIS	Low-Income Subsidy
MMIS	Medicaid Management Information System
MTM	Medication Therapy Management
SNAP	Supplemental Nutrition Assistance Program
TANF	Temporary Assistance for Needy Families
WIR	Wisconsin Immunization Registry

I. EXECUTIVE SUMMARY

The University of Wisconsin-Madison (UW) will evaluate the State of Wisconsin's SeniorCare Pharmaceutical Benefit for Low-Income Seniors, as approved by the federal Centers for Medicare and Medicaid Services (CMS) under a § 1115 waiver. The waiver was approved for a ten-year period, from 2019-2028, and this proposed evaluation is designed to answer hypotheses using data from the first five-year period, from 2019-2023. (Note: After five years of operating and evaluating the waiver evaluation, DHS will assess the program, the observed outcomes, and the environment, to consider new hypotheses and evaluation questions for the second five year period.) This evaluation will involve a range of health services and econometric methods, and rely on state and national administrative claims data. The evaluation will address the following three hypotheses and associated research questions, along with relevant data and analytic methods:

Hypothesis 1: SeniorCare will have a positive effect on member medication use and financial hardship.

Q1-1: How does the SeniorCare population compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and statistical tests using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Q1-2: How do annual trends in drug utilization and expenditures in SeniorCare compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare and similar Part D enrollees. Outcomes will be assessed in detail for important drug types and therapeutic classes.

Q1-3: How does the prevalence of financial hardship among SeniorCare members compare to similar populations of older adults?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Hypothesis 2: SeniorCare will have a positive effect on the health outcomes of Wisconsin seniors.

Q2-1: How does the quality of medication use (medication safety, adherence and appropriate use) in SeniorCare compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Various quality measures endorsed by CMS and the PQA will be applied for analyses of drug utilization of certain drug therapeutic classes and chronic conditions. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Q2-2: How does the health status of SeniorCare members compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Q2-3: How do annual trends in health care services utilization and expenditures in the SeniorCare population compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Q2-4: What are annual trends in Comprehensive Medication Review and Assessment (CMR/A) utilization and expenditures in SeniorCare?

- Descriptive statistics and statistical tests using enrollment and claims data from SeniorCare.

Q2-5: Are there changes in adherence to recommended vaccine schedules among SeniorCare members after the initiation of SeniorCare vaccination coverage?

- Descriptive statistics and statistical tests using enrollment and claims data from SeniorCare and Wisconsin Immunization Registry (WIR) data.

Hypothesis 3: SeniorCare will reduce the likelihood of Medicaid entry and provide cost savings to the Wisconsin Medicaid program.

Q3-1: How does SeniorCare enrollment impact an individual's likelihood of Medicaid entry?

- Descriptive statistics and regression analysis, using enrollment and claims data from SeniorCare, Medicare, and Medicaid

Q3-2: How does SeniorCare enrollment impact an individual's use of Medicaid-funded nursing home care?

- Descriptive statistics and time-to-event models using SeniorCare enrollment data and Medicaid enrollment and nursing home claims

Q3-3: What would Medicaid expenditures be in the absence of the SeniorCare program?

- Cost modeling using a generalized linear model (GLM), using SeniorCare enrollment and claims, Medicare enrollment and claims, and Medicaid claims data

II. DEMONSTRATION WAIVER AND EVALUATION BACKGROUND

The UW Institute for Research on Poverty (IRP) is conducting an evaluation of the Wisconsin SeniorCare Pharmaceutical Benefit for Low-Income Seniors, as proposed by the Wisconsin Department of Health Services (DHS) and approved by the federal Centers for Medicare and Medicaid Services (CMS).

A. Waiver Overview and Target Populations

The Wisconsin Department of Health Services has received a CMS-approved Section 1115 demonstration waiver to continue its longstanding SeniorCare Prescription Drug Assistance Program. The newly approved waiver authorizes an additional ten-year period for the program, from January 1, 2019, to December 31, 2028. The demonstration-eligible population includes individuals age 65 or over with income at or below 200% of the federal poverty level (FPL), who are otherwise not receiving full Medicaid benefits.

A1. Background

On July 1, 2002, the Department received the necessary waiver approvals from CMS to operate a portion of SeniorCare, a prescription drug benefit for seniors, as a five-year demonstration project. The SeniorCare waiver extends Medicaid eligibility through Title XIX to cover prescription drugs as a necessary primary health care benefit. The target population for services under the SeniorCare waiver program is seniors who are age 65 or older with income at or below 200% FPL.

Under the terms of the waiver, SeniorCare has complied with federal and state laws and regulations (except those for which a specific waiver is requested) for Medicaid eligibility, benefits, and administration, including application processing, claims processing, federal reporting, and safeguards for fraud and abuse.

As of 2019, Wisconsin has a CMS-approved 10-year section 1115 waiver to continue operating the SeniorCare program, and to receive Medicaid federal matching funds for individuals who qualify for SeniorCare. Wisconsin will continue to provide the SeniorCare prescription drug benefit to low-income seniors.

Under the continuation waiver, Wisconsin residents who are ages 65 or older, not currently eligible for Medicaid benefits, and whose income does not exceed 200% FPL are eligible for coverage of legend drugs and over-the-counter insulin as currently provided under the Wisconsin Medicaid State Plan. Those seniors with prescription drug coverage under other plans are also eligible to enroll, with SeniorCare covering eligible costs not covered under other plans. There is no asset test.

Members pay an annual $30 enrollment fee. Individuals with income at or below 160% FPL are responsible for a copayment of $15 for each brand name prescription and $5 for each generic prescription. Individuals with an income above 160% and less than 200% FPL are also responsible for the first $500 of prescription drug costs each year at the SeniorCare rate.

Members may begin participation in the program on the first day of the month following the month in which all eligibility criteria are met. Once determined eligible for the SeniorCare program, an individual may remain eligible for 12 months from the date of initial enrollment, regardless of changes in income.

SeniorCare, similar to Medicaid, must coordinate eligibility across programs and coordinate with benefits covered by other insurers.

A2. SeniorCare Objectives

The CMS-approved 2019 waiver identifies the program provisions, objectives, and Special Terms and Conditions, included here in Attachment A.

The demonstration waiver is expected to continue to promote the following goals:

- Keeping Wisconsin seniors healthy by continuing to provide a necessary primary health care benefit;
- Reducing the rate of increase in the use of non-pharmacy related services provided to this population including hospital, nursing facility and other non-pharmacy related medical services; and,
- Helping control overall costs for the aged Medicaid population by preventing or delaying seniors from becoming eligible for Medicaid due to deteriorating health and spending down to Medicaid eligibility levels.

A3. Eligibility Requirements

To be eligible for prescription drug services under the SeniorCare waiver program, individuals must meet all of the following requirements:

1. Be a Wisconsin resident;
2. Be a U.S. citizen or have qualifying immigrant status;
3. Not be Medicaid enrolled other than as a low-income Medicare beneficiary (QMB, SLMB, QI-1 or QDWI);
4. Be age 65 or older;
5. Have household income at or below 200% FPL; and
6. Pay the applicable annual enrollment fee of $30 per person.

Individuals with a household income above 200% FPL receive program benefits after they have met program requirements for deductible and spenddown, if required. Income is calculated as follows:

- A gross income test is used, except in cases of self-employment income. The standard Elderly, Blind or Disabled (EBD) Medicaid deductions and other deductions are not applied.
- In cases of self-employment income, current policy for Medicaid EBD is followed. Therefore, deductions for business expenses, losses and depreciation are permitted for individuals with self-employment income.
- Income is determined on a prospective basis, annually.
- A fiscal test group that is consistent with current Medicaid EBD policy is used. Thus, individual income is used for a married person not living with his or her spouse, and joint income is used for a married person living with his or her spouse. These income amounts are compared to the FPL for a group size of one if counting only the income of the individual, or for a group size of two if counting the income of the applicant and his or her spouse.
- There is no asset test related to eligibility for the SeniorCare waiver program.

A4. Application Process for SeniorCare Benefits

The application process for eligible seniors involves the following components:

- The senior completes the simple, short application.
- The senior submits the application by regular mail.
- The application is processed by a central unit administered by the Department.
- Near the end of the individual's year of eligibility, the Department notifies him or her of the need for an annual re-determination of his or her eligibility. The Department provides the individual with a pre-printed renewal form containing some of the information provided in the previous year. To continue coverage, the form must be filed in a timely manner and receive approval. The individual must also pay the annual enrollment fee.
- Upon enrollment, the SeniorCare waiver program member receives an identification card distinct from the current ForwardHealth card. Members must present the identification card to the pharmacy or pharmacist when purchasing prescription drugs.

A5. Enrollment Periods

Enrollment periods for eligible members are as follows:

- Once determined eligible for the SeniorCare waiver program, an individual may remain eligible for 12 months from the date of initial enrollment, regardless of changes in income. However, if a person permanently leaves Wisconsin or becomes deceased, he or she is no longer eligible for the SeniorCare waiver program.
- Members may reapply if their income decreases. For example, if an individual with income at or above 165% FPL subsequently loses a part-time job resulting in income below 160% FPL, the individual may reapply. In this situation, the individual would no longer be required to pay the first $500 in prescription drug costs but would need to pay a new $30 enrollment fee to establish a new 12-month benefit period.
- An individual is able to begin participation in the program on the first day of the month following the month in which all eligibility criteria are met.
- Eligibility for benefits is prospective only. There is no retroactive eligibility.

A6. Coordination of Benefits

The SeniorCare waiver program extends coverage only to legend (prescription) drugs and to over-the-counter insulin; these are drugs that are currently covered by the Wisconsin Medicaid State Plan. SeniorCare is the payer of last resort for covered services; coordination of benefits is applied in a manner similar to the Medicaid program. The SeniorCare waiver program uses a combination of automated, pre-payment cost avoidance within the point of service (POS) system and, where necessary, will bill liable third parties after the payment is made.

If a person is eligible to receive medication therapy management (MTM) services through commercial insurance and/or Medicare, the pharmacist is required to submit the MTM claims to other payers.

A7. Cost Sharing

SeniorCare members are required to comply with cost-sharing provisions that vary by income level. The following describes the cost-sharing features in more detail.

Annual Enrollment Fee

All SeniorCare members are required to pay an annual enrollment fee of $30. Once determined eligible for SeniorCare, an applicant will receive a letter notifying him or her of the eligibility and cost-sharing requirements. All applicants have the option to decline participation if they notify the Department within the 30-day processing period or within 10 days of the date on the letter, whichever is later. If an individual declines participation within this time period, the Department will refund the enrollment fee paid for that benefit period. If an individual has paid the annual enrollment fee with his or her application and is determined ineligible for the program, the Department will refund the paid enrollment fee.

Annual Costs for Members

Certain SeniorCare members pay the first $500 in prescription drug costs each enrollment period at the SeniorCare rate.

- SeniorCare members with income between 160% and 200% FPL are responsible for the first $500 of prescription drug costs per year. The first $500 will be paid by the member at the SeniorCare rate.
- If SeniorCare members chooses to receive MTM services and their income is between 160% and 200% FPL, they are responsible for paying Medicaid rates for the MTM services while in the $500 deductible period. Member payments toward MTM services will count toward the member's deductible.
- SeniorCare members with income at or below 160% FPL are not required to pay a $500 deductible for prescription drug costs or MTM services.

Co-Payments

For SeniorCare members with income above 160% FPL who have met the $500 annual deductible, and for members with income at or below 160% FPL, a copayment is-required for each prescription drug for the remainder of that 12-month period. The following copayments apply:

- $15 copayment per prescription for brand name drugs.
- $5 copayment per prescription for generic drugs.

There is no copayment for MTM services.

A8. Coordination with Other Medicaid Programs

The following are stipulations regarding coordination between the Medicaid program and the SeniorCare waiver program:

- SeniorCare members whose income decreases to allowable Medicaid eligibility levels and who want to receive full Medicaid benefits must apply for and be determined eligible for full-benefit Medicaid through the normal Medicaid application process.
- Except during the 30-day initial processing period, the enrollment fee is not refundable to SeniorCare members who, during their 12-month benefit period, become eligible for full Medicaid benefits. However, SeniorCare will remain open to these individuals. Thus, if they subsequently become ineligible for full Medicaid benefits during the 12 months, they will automatically be able to receive SeniorCare benefits for the remainder of the 12-month period without having to pay another $30 fee.
- SeniorCare members who are terminated from the SeniorCare program or who fail to re-enroll will not be reviewed for eligibility for other Medicaid programs prior to termination.

A9. Benefits

Pharmaceuticals

Wisconsin Medicaid covers legend drugs and over-the-counter insulin prescribed by a licensed physician, dentist, podiatrist, nurse prescriber, or ophthalmologist as currently provided under the Wisconsin Medicaid State Plan. In addition, physicians may delegate prescription authority to a nurse practitioner or physician assistant.

Wisconsin Medicaid has an open drug formulary. This means that legend drugs or over-the-counter

insulin are covered if they meet all of the following criteria:

- The drug is Food and Drug Administration (FDA)-approved;
- The manufacturer signed a rebate agreement with CMS; and
- The manufacturer has reported data and prices to First DataBank (a national drug database).

SeniorCare statutes define prescription drugs as prescription drugs covered by Wisconsin Medicaid and for which the drug manufacturers enter into a rebate agreement with the state. However, like Wisconsin Medicaid, SeniorCare extends coverage to over-the-counter insulin.

Medication Therapy Management (MTM)

The Medication Therapy Management (MTM) benefit consists of private consultations between a pharmacist and a member to review the member's drug regimen, as currently provided under the Wisconsin Medicaid State Plan.

Comprehensive Medication Review and Assessment (CMR/A) allow specially trained pharmacists to review a member's drug regimen. Members who are at a high risk of experiencing medical complications due to their drug regimen are eligible for this service. During the CMR/A, the pharmacist may:

- Obtain the necessary assessments of the member's health status;
- Formulate a medication treatment plan for the member;
- Provide information, support services and resources designed to enhance member adherence with the member's therapy regimens;
- Document the care delivered and communication of essential information to the member's primary care providers;
- Refer the member to an appropriate health care provider if necessary; or
- Coordinate and integrate medication management services within the broader health care system.

There is a limit of one initial and three follow-up CMR/As per year. Pharmacists may request an exemption from these limits.

Vaccinations

Beginning in 2021, SeniorCare will cover all vaccinations recommended for older adults by the federal Centers for Disease Control and Prevention. This coverage is authorized by 2019 Wisconsin Act 185, enacted on April 16, 2020.[1] DHS will provide payments to pharmacies that administer the vaccinations and submit claims for payment in the manner required. Additionally, DHS may provide payment for a vaccination only after deducting the amount of any payment for the vaccination available from other sources.

[1] For background, see: https://docs.legis.wisconsin.gov/misc/lc/information_memos/2020/im_2020_05

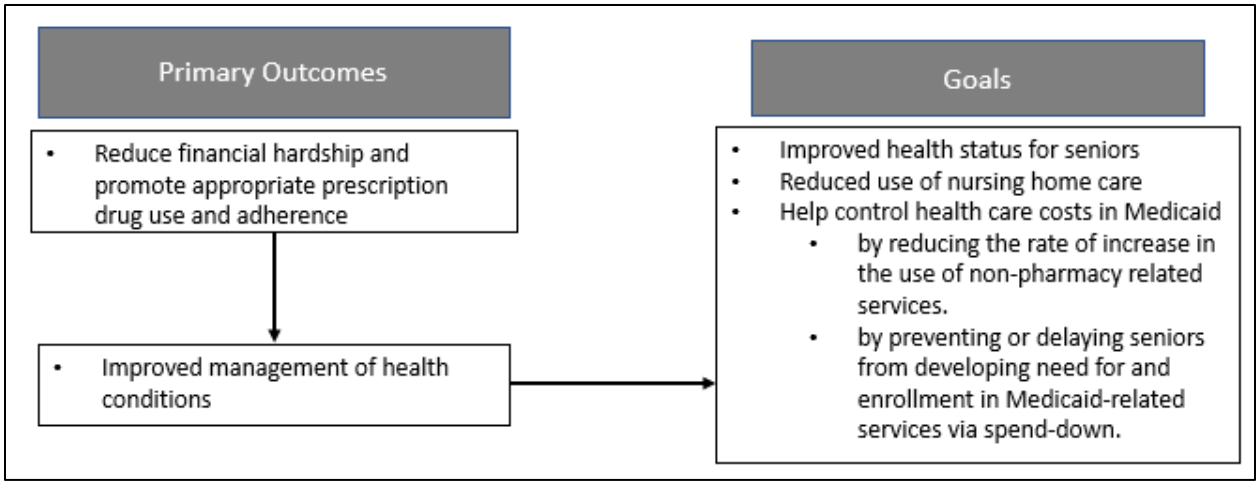
B. Evaluation Team Background and Qualifications

Our team has conducted and published studies on a broad range of prescription-drug and Medicaid-related evaluation and research topics. Sponsors of this team's work include the state and federal governments, foundations, and private sector concerns. We conducted the evaluation of Wisconsin's SeniorCare prescription drug program under the 2016-18 demonstration waiver project period, and we have contributed to the CMS-required evaluation of Wisconsin's BadgerCare § 1115 waiver during the 2014-2018 project period. The team is based at the UW-Madison, with collaborating faculty investigators at the UW School of Pharmacy and at the Medical College of Wisconsin, supported by research and data programming staff based at the UW Institute for Research on Poverty.

III. EVALUATION QUESTIONS AND HYPOTHESES

A. Driver Diagram

Figure III.A.1. Driver Diagram for SeniorCare Pharmaceutical Benefit



B. Waiver Goals: Relationship to Hypotheses and Questions

CMS, within the waiver approval Special Terms and Conditions document, has identified the following goals for the SeniorCare demonstration waiver:

- Keep Wisconsin seniors healthy by continuing to provide a necessary primary health care benefit;
- Reduce the rate of increase in the use of non-pharmacy related services provide to this population, including hospital, nursing facility and other non-pharmacy related medical services; and
- Help control overall costs for the aged Medicaid population by preventing or delaying seniors from becoming eligible for Medicaid due to deteriorating health and spending down to Medicaid eligibility levels.

The hypotheses and research questions articulated here grow directly from these goals and drive the evaluation plan:

Hypothesis 1: SeniorCare will have a positive effect on member medication use and financial hardship.

Q1-1: How does the SeniorCare population compare to older adults enrolled in Medicare Part D?

Q1-2: How do annual trends in drug utilization and expenditures in SeniorCare compare to older adults enrolled in Medicare Part D?

Q1-3: How does the prevalence of financial hardship among SeniorCare members compare to similar populations of older adults?

Hypothesis 2: SeniorCare will have a positive effect on the health outcomes of Wisconsin seniors.

Q2-1: How does the quality of medication use (medication safety, adherence and appropriate use) in SeniorCare compare to older adults enrolled in Medicare Part D?

Q2-2: How does the health status of SeniorCare members compare to older adults enrolled in Medicare Part D?

Q2-3: How do annual trends in health care services utilization and expenditures in the SeniorCare population compare to older adults enrolled in Medicare Part D?

Q2-4: What are annual trends in Comprehensive Medication Review and Assessment (CMR/A) utilization and expenditures in SeniorCare?

Q2-5: Are there changes in adherence with recommended vaccine schedules among SeniorCare members after the initiation of SeniorCare vaccination coverage?

Hypothesis 3: SeniorCare will reduce the likelihood of Medicaid entry and provide cost savings to the Wisconsin Medicaid program.

Q3-1: How does SeniorCare enrollment impact an individual's likelihood of Medicaid entry?

Q3-2: How does SeniorCare enrollment impact an individual's use of Medicaid-funded nursing home care?

Q3-3: What would Medicaid expenditures be in the absence of the SeniorCare program?

IV. METHODOLOGY

A. Evaluation Design Summary

The best available data will be used to evaluate the demonstration project using the prevailing standards of scientific and academic rigor. Each of the hypotheses depend on different data sources and require different analytic methods, which will be used to provide a comprehensive assessment of the evaluation questions. The evaluation design includes the analysis of existing secondary data (e.g., enrollment and claims data). Given the longitudinal nature of the SeniorCare program, multiple cross-sectional and longitudinal analyses will be conducted to assess the evaluation measures and changes in these measures over time. Comparable data on appropriate comparison groups composed of similar populations of low-income seniors will be included whenever possible to enhance the rigor of the analyses.

The Design Table (Table IV.A.1.) summarizes the key features of the evaluation design, including the primary research questions for each hypothesis, example outcome measures, target populations, data sources, and analytic methods for each question. The narrative that follows provides more detail about each of these items.

The target population of this evaluation is the entire SeniorCare population covered by the section 1115 waiver. In order to make relevant and meaningful comparisons, the evaluation will focus on key subgroups of SeniorCare members, such as SeniorCare members who do not have other sources of prescription drug coverages (e.g., SeniorCare only) and SeniorCare members who have Medicare Part D (e.g., SeniorCare plus Part D). We will also compare study outcomes to Medicare Part D members who do not have SeniorCare or other sources of prescription drug coverage (e.g., Part D only) and if feasible, the subgroup of Part D enrollees that are Low-Income Subsidy recipients. Propensity score matching will be used whenever possible for constructing the most comparable group of Part D enrollees to the SeniorCare population. More details on the study populations are available in section B. Target and Comparison Populations.

Table IV.A.1. Evaluation Design Table

Research Question	Outcome Measures	Population	Data Sources	Analytic Methods
Hypothesis 1: SeniorCare will have a positive effect on member medication use and financial hardship				
Q1-1: How does the SeniorCare population compare to older adults enrolled in Medicare Part D?	-Demographic characteristics (e.g., age, gender, race/ethnicity) -Socioeconomic status (e.g., annual income)	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroup of SeniorCare members with Part D	-SeniorCare enrollment and claims data -Medicare enrollment and claims data	-Descriptive statistics -Comparisons between SeniorCare members and Medicare Part D enrollees (e.g., chi-squared test and student t-test)
Q1-2: How do annual trends in drug utilization and expenditures in SeniorCare compare to older adults enrolled in Medicare Part D?	-Trends in drug utilization (e.g., annual number of total drug fills, annual proportion of enrollees who had any drug fills, etc.) -Trends in expenditures (e.g., total drug costs, SeniorCare drug costs, member out-of-pocket costs, drug costs by other payers, etc.) -Trends in utilization and expenditures for brand and generic drugs; -Trends in utilization and expenditures for specialty and non-specialty drugs -Trends in utilization and expenditures for common therapeutic drug classes	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroup of SeniorCare members with Part D	-SeniorCare enrollment and claims data -Medicare enrollment and claims data	-Descriptive statistics -Time-series models -Comparisons between SeniorCare and Medicare Part D enrollees

Q1-3: How does the prevalence of financial hardship among SeniorCare members compare to similar populations of older adults?	-Trends in the prevalence of claims-based measures of financial burden (e.g., total out-of-pocket costs, ratio of out-of-pocket costs to income, etc.)	-Entire SeniorCare population -Comparison group of older adults with Part D	-SeniorCare enrollment and claims data -Medicare enrollment and claims data	-Descriptive statistics -Comparisons between SeniorCare and non-SeniorCare enrollees -Time-series models
Hypothesis 2: SeniorCare will have a positive effect on the health outcomes of Wisconsin seniors				
Q2-1: How does the quality of medication use (medication safety, adherence and appropriate use) in SeniorCare compare to older adults enrolled in Medicare Part D?	-Adherence to medications for chronic conditions -Statin use in persons with diabetes -Use of high-risk medications in the elderly (e.g., opioids, benzodiazepines, polypharmacy, etc.)	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroup of SeniorCare members with select chronic conditions	-SeniorCare enrollment and claims data -Medicare enrollment and claims data -Pharmacy Quality Alliance (PQA) performance measures and value sets	-Descriptive statistics -Time-series models with control groups -Comparisons between SeniorCare and Medicare Part D enrollees
Q2-2: How does the health status of SeniorCare members compare to older adults enrolled in Medicare Part D?	-Number and type of chronic health conditions -Claim-based measures of health status (e.g., Charlson Comorbidity Index, Elixhauser Index, or Rx-Risk Comorbidity Index)	-Entire SeniorCare population -Comparison group of older adults with Part D	-SeniorCare enrollment and claims data -Medicare enrollment and claims data	-Descriptive statistics -Time-series models -Comparisons between SeniorCare and Medicare Part D enrollees

Q2-3: How do annual trends in health care services utilization and expenditures in the SeniorCare population compare to older adults enrolled in Medicare Part D?	-Utilization of health care services -Costs for health care services -Cumulative probability of remaining outside the hospital -Likelihood of hospital admission or emergency department use	-Entire SeniorCare population -Comparison group of older adults with Part D	-SeniorCare enrollment and claims data -Medicare enrollment and claims data	-Descriptive statistics -Time-series models -Comparisons between SeniorCare and Medicare Part D enrollees
Q2-4: What are annual trends in Comprehensive Medication Review and Assessment (CMR/A) utilization and expenditures in SeniorCare?	-Utilization of CMR/A services (e.g., number of CMR/A claims, members who received CMR/A, etc.) -Expenditures for CMR/A services (e.g., annual total costs for CMR/A, annual SeniorCare and member costs, mean costs per member, etc.)	-Entire SeniorCare population	-SeniorCare enrollment, drug claims, and MTM claims data	-Descriptive statistics -Annual trends
Q2-5: Are there changes in adherence with recommended vaccine schedules among SeniorCare members after the initiation of SeniorCare vaccination coverage?	-Utilization of vaccinations (e.g., number of vaccinations, members who had vaccinations, etc.) -Expenditures for vaccinations (e.g., total costs, SeniorCare program costs, and member out-of-pocket costs)	-Entire SeniorCare population	-SeniorCare enrollment and vaccination claims data -Wisconsin Immunization Registry (WIR) data	-Descriptive statistics -Pre-post comparison after implementation of vaccination coverage

Hypothesis 3: SeniorCare will reduce the likelihood of Medicaid entry and provide cost savings to the Wisconsin Medicaid program.				
Q3-1: How does SeniorCare enrollment impact an individual's likelihood of Medicaid entry?	-Cumulative rate of Medicaid entry	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroup of SeniorCare members with Part D	-SeniorCare enrollment and claims data -Medicaid enrollment and claims data -Medicare enrollment and claims data	-Descriptive statistics -Regression models such as Cox proportional hazard or competing risks model
Q3-2: How does SeniorCare enrollment impact an individual's use of Medicaid-funded nursing home care?	-Utilization of nursing home care -Costs for nursing home care -Cumulative probability of remaining outside a nursing home[2] -Likelihood of transitioning to a nursing home	-SeniorCare members who used nursing home care -Comparison group of older adults in Medicaid EBD population -Subgroup of SeniorCare members with Part D	-SeniorCare enrollment data -Medicaid enrollment and nursing home claims	-Descriptive statistics -Comparisons between SeniorCare and non-SeniorCare enrollees -Time-to-event models (discrete time hazard models using a logistic regression and/or a Cox proportional hazard model)
Q3-3: What would Medicaid expenditures be in the absence of the SeniorCare program?	-Estimated Medicaid costs for SeniorCare members	-Entire SeniorCare population	-SeniorCare enrollment and claims data -Medicare enrollment and claims data -Medicaid claims data	-Cost modeling using a GLM with appropriate link and family selected using a modified Park test -Predicted spending adjusted using marginal standardization

[2] Soumerai SB, Ross-Degnan D, Avorn J, McLaughlin TJ, Choodnovskiy I. 1991. Effects of Medicaid drug-payment limits on admission to hospitals and nursing homes. New England Journal of Medicine 325(15):1072-1077. https://www.nejm.org/doi/full/10.1056/NEJM199110103251505

B. Target and Comparison Populations

Analyses will be conducted from a variety of perspectives to provide a comprehensive understanding of the impact of the SeniorCare program. The target population consists of all members enrolled in the SeniorCare waiver program during the evaluation period. Program-level analyses of the entire SeniorCare population will be conducted to understand broad characteristics of the program and how it interacts with other public insurance programs (i.e., Medicare and Medicaid). Additional member-level analyses will be conducted to provide a more detailed understanding of these outcomes, as well as the impact of the SeniorCare program on member medication use, expenses, and health outcomes.

The program-level analyses will primarily include all SeniorCare members enrolled in the waiver program during the evaluation period. Certain longitudinal member-level analyses will focus on the continuously enrolled population, as the most complete information is available for these members. Subgroups of interest for stratified analyses include SeniorCare members with supplemental drug coverage (e.g., both SeniorCare and Part D), rural and urban populations, members with chronic conditions, and members receiving MTM services. Annual or monthly measures will be used whenever possible for the evaluation measures; if there is insufficient sample size for the subgroups, pooled analyses over larger time periods will be used to ensure statistically reliable sample sizes are available.

Multiple comparison groups consisting of similar populations of low-income older adults will be used whenever possible to enhance the rigor of the analyses and better identify the impact of the SeniorCare program. The selection of an appropriate comparison group will vary for each evaluation measure, and the decision will be based on the comparability, feasibility, and availability of data for the various groups. The following groups will be considered as comparison groups to the SeniorCare waiver population: 1) the non-waiver SeniorCare population (i.e., members with income >200% FPL); 2) older adults enrolled in Medicare Part D (including those receiving the low-income subsidy) that have never enrolled in SeniorCare, including Part D enrollees in Wisconsin and other states; and 3) older adults in the Wisconsin Medicaid EBD population who have never enrolled in SeniorCare.

Evaluation Period

Data from January 1, 2016 to December 31, 2023 will be used to address the evaluation measures. This period includes 3 years prior to and the first half of the approved waiver period (calendar years 2019-2023). The time period will vary for each evaluation measure and upon data availability from vendors. Data from the Wisconsin Department of Health Services on the SeniorCare and Medicaid populations are typically available on a regular and timely basis; in contrast, external data sources (i.e., Medicare data) typically have a lag of 14 months for data collection, cleaning, and imputation of missing data. Therefore, some analyses may consist of a cross-section in time, several years of data, or the entire evaluation period.

C. Data Sources and Outcome Measures

Table IV.A.1, above, displays the outcome measures for each question. This evaluation will involve multiple data sources, including state and national administrative data. They are noted in Table IV.C.1, along with the hypotheses for which these data will be used. Whenever possible, validated or commonly used measures will be utilized to allow for comparisons between the SeniorCare population and other older adult populations in the literature. The following narrative provides more information on each of the data sources that will be used to conduct the evaluation.

Table IV.C.1. Data Sources and Associated Hypotheses

Data Sources	Hypotheses
SeniorCare Data	H1, H2, H3
Medicaid Data	H3
Medicare Data	H1, H2, H3
Wisconsin Immunization Registration Data	H2

SeniorCare Data: SeniorCare administrative, enrollment, and claims data over the entire waiver period will be used to obtain information on program enrollment, utilization, and expenditures. These data will be used to obtain information on the target population (SeniorCare waiver members) as well as the SeniorCare non-waiver comparison group. The enrollment data reside in the Wisconsin CARES system, a state-operated data warehouse that includes all eligibility-related information pertaining to members of Medicaid and SeniorCare. Claims data reside in the state's Medicaid Management Information System (MMIS). These data provide detailed and complete information on all drug claims paid by the SeniorCare program. However, although these data provide limited information on paid amounts from other payers, they do not provide detailed information on the identities of other payer(s) or drugs obtained from sources other than the SeniorCare benefit (e.g., through other insurance or obtaining a drug without using insurance). These data also do not provide information on what happens to disenrolled members after they leave SeniorCare. In addition, because the SeniorCare benefit only provides prescription drug insurance, there is no information on health care utilization.

Medicaid Data: Medicaid administrative, enrollment, claims, and encounter data over the entire waiver period will be used to obtain data for the older adult Medicaid EBD population (i.e., elderly beneficiaries with full-benefit Medicaid). Wisconsin CARES is the state's online eligibility and enrollment portal for public benefits, including Medicaid, TANF, and FoodShare (SNAP). We will use data from CARES to obtain longitudinal administrative data pertaining to enrollment. Demographic information includes age, sex, educational attainment, county of residence, income, and income sources.

Wisconsin Medicaid claims and encounter data come from the State's MMIS claims database. These data contain detailed information on diagnoses, procedure, and billing codes from which we will construct outcome measures of health care use, as well as paid amounts for covered services.

These data will be used to assess the use of nursing home and long-term care services by those enrolled in SeniorCare, and to identify individuals that transitioned between SeniorCare and Medicaid. In addition, the older adult Medicaid EBD population will be used as a comparison group to the SeniorCare waiver population. The enrollment and claims data reside in the Wisconsin CARES system and MMIS as described above. These data provide detailed and complete information on all claims paid by the Medicaid program, which is the primary payer of nursing home care in the US.[3] However, these data do not provide detailed information from other payer(s), which is particularly relevant for dual-eligibles covered by both Medicare and Medicaid.

Medicare Data: Medicare administrative, enrollment, and claims data will be obtained for Medicare Parts A, B, and D. Data will be obtained for a 100% sample of Wisconsin Medicare beneficiaries in addition to a 5% national sample of Medicare beneficiaries over a 6-year period. Medicare is the primary provider of health insurance coverage for SeniorCare members; therefore, these data will be used to obtain information on the use of inpatient and outpatient health services covered by traditional fee-for-service Medicare (Parts A and B). Medicare Part D data will be used to supplement the SeniorCare claims and obtain more detailed information on drug use for SeniorCare members enrolled in both programs.

The Medicare data will also be used to construct appropriate comparison groups to the SeniorCare waiver population of older adults who have Medicare Part D as their primary source of prescription drug insurance coverage. These comparison groups include older adults in the general Medicare population both in Wisconsin and nationally, as well as a subsample of Medicare beneficiaries receiving the LIS. The Medicare data will be obtained from the CMS Chronic Conditions Data Warehouse (CCW), which provides researchers with Medicare and Medicaid beneficiary, claims, and assessment data linked by beneficiary across the continuum of care. The CCW is a research database designed to make Medicare, Medicaid, Assessments, and Part D Prescription Drug Event data more readily available to support research designed to improve the quality of care and reduce costs and utilization.

These data provide detailed and complete information on all claims paid by the Medicare program, which is the primary source of health insurance coverage for older adults in the US. These data can also be linked to state Medicaid data to allow for tracking of these individuals across multiple programs (i.e., SeniorCare, Medicaid, and Medicare). However, these data are only available for individuals enrolled in traditional fee-for-service Medicare (Parts A, B, and D) and are not available for individuals enrolled in Medicare Advantage managed care plans (Part C). Thus, complete information may not be available for all SeniorCare members. In 2018, around 34% of total Medicare beneficiaries were enrolled in Part C.[4] In addition, there is also a lag of approximately 14 months between data collection and data availability.

[3] Kaiser Family Foundation. 2017. "Medicaid's Role in Nursing Home Care." Kaiser Family Foundation Infographic. Issued June 20, 2017. www.kff.org/infographic/medicaids-role-in-nursing-home-care/

[4] Kaiser Family Foundation. An Overview of Medicare. Issued Feb 13, 2019 https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/

Wisconsin Immunization Registry Data[5]: The Wisconsin Immunization Registry (WIR) is a computerized internet database maintained by the Wisconsin DHS to record and track immunization records for Wisconsin residents. It allows health care providers to record and track patients' vaccine records and make sure they receive vaccines on time according to recommended schedules. Patients also can look up their own or their children's immunization records.

Although it is not mandatory for all health care providers that administer vaccines to use the WIR, approximately 3,700 providers and 2,400 schools and school districts across Wisconsin have implemented the WIR.[6] In addition, pharmacists are required under Wisconsin statutes to report immunizations in WIR for immunizations administered to individuals aged 6-18 years within 7 days of administration. As one of the initiatives to encourage adoption and meaningful use of electronic health records, CMS has established an incentive program for health care providers and hospitals to connect their electronic health records with immunization information systems such as the WIR.[7] According to a study comparing medical records with WIR records among children born in 2009, the WIR record showed good completeness and accuracy; 97% of the vaccinations were documented in the WIR, 99% had the same administration date, and 96% had the same trade name.[8]

The WIR receives demographic information and vaccination records from multiple sources: Wisconsin Divisions of Public Health Vital Records Office, manual data entry into the WIR database, electronic health records, and billing systems. WIR may also receive immunization record from patients even when their providers did not submit data to the WIR.[8]

As multiple options are available to SeniorCare members for vaccination coverage (e.g., Medicare Part B, C, or D), SeniorCare data will not provide complete information on all vaccinations administered to members. The WIR data can provide dates and names of vaccinations administered to Wisconsin residents, regardless of the types of providers or insurance coverage. It can also provide the immunization data in near real-time with a relatively short time lag (e.g., around 7 days). However, the WIR data does not have payer information, such as source of coverage, covered amount, and copay amount.

D. Analytic Methods

An overview of the primary analytic methods for each hypothesis and research question are included in the Design Table IV.A.1, along with example outcome measures, target and comparison populations,

[5] See https://www.dhs.wisconsin.gov/immunization/wir-healthcare-providers.htm
[6] See https://www.dhs.wisconsin.gov/publications/p02451.pdf
[7] Engstrom, et al. Timeliness of data entry in Wisconsin Immunization Registry by Wisconsin pharmacies. J Am Pharm Assoc (2003) . Jul-Aug 2020;60(4):618-623. https://pubmed.ncbi.nlm.nih.gov/31953117/
[8] Ruth et al. Completeness and Accuracy of the Wisconsin Immunization Registry: An Evaluation Coinciding With the Beginning of Meaningful Use. J Public Health Manag Pract. May-Jun 2015;21(3):273-81. https://www.medicine.wisc.edu/sites/default/files/completeness_and_accuracy_of_wisconsin_conway.pdf

and data sources. The following section provides a more detailed overview for each individual hypothesis and research question.

The evaluation of the demonstration waiver will involve a variety of analytic approaches. Descriptive analyses will be used for all analyses to provide cross-sectional snapshots and longitudinal trends in the outcomes for the SeniorCare population. Whenever possible, one or more comparison groups will be used to allow for more rigorous analytic techniques, and multivariate analyses will be used to control for potential confounders. Sensitivity analyses will be performed for all analyses to assess the responsiveness of the results to changes in the assumptions used in the primary analyses.

Hypothesis 1: SeniorCare will have a positive effect on member medication use and financial hardship

Q1-1: How does the SeniorCare population compare to older adults enrolled in Medicare Part D?

Medicare Part D was implemented on January 1, 2006 as a voluntary prescription drug insurance benefit for older adults in the Medicare program. SeniorCare is considered creditable coverage, which means it is considered to be as good as the standard Medicare Part D plan. However, older adults in Wisconsin have the opportunity to enroll in one or both programs given their individual needs and preferences. Given the possibility of self-selection into these programs, it is important to understand the different populations covered by the two programs and how they compare in terms of demographic and socioeconomic characteristics. In addition, previous evaluations of the SeniorCare program have found increasing use of SeniorCare as supplementary coverage to other sources of drug coverage. Therefore, we will also evaluate the subgroup of SeniorCare members who are also enrolled in Medicare Part D.

Outcomes

We will assess and compare the number of enrollments and demographic and socioeconomic characteristics of the SeniorCare, Medicare Part D, and dually enrolled members for each calendar year.

Data

SeniorCare and Medicare eligibility and enrollment data will be used to obtain information on the demographic and socioeconomic status of enrollees in the two programs.

Statistical Analysis

Descriptive statistics will be used to summarize the characteristics of each study group for various time periods. Comparisons between the various populations (SeniorCare only, Medicare Part D only, SeniorCare + Part D) will be made using appropriate statistical tests such as chi-squared tests, t-tests, ANOVA, and/or ANCOVA.

Q1-2: How do annual trends in drug utilization and expenditures in SeniorCare compare to older adults enrolled in Medicare Part D?

When Medicare Part D was implemented on January 1, 2006 additional prescription drug coverage options became available to SeniorCare members. SeniorCare is considered creditable coverage, which means it is considered to be as good as the standard Medicare Part D plan. However, it is unknown how the SeniorCare and Medicare Part D programs compare on a variety of domains related to the utilization of and expenditures for prescription drugs. Analyzing and comparing trends in the use of various types of drugs (e.g., brand, generic, specialty, etc.) and the associated expenditures will improve our understanding of how the program has performed over time, and can inform policies and programs promoting cost-effective drug use.

Outcomes

Trends (e.g., annual and monthly) in drug utilization will be evaluated, including outcomes such as total and mean drug fills, 30-day adjusted drug fills, and proportion of enrollees with at least one drug fill. Trends in drug expenditures will be evaluated from multiple perspectives, including total and mean expenditures from all sources of payment, SeniorCare program costs, and member out-of-pocket costs. In addition, drug utilization and expenditures will be assessed in detail for a variety of important drug types, including brand name vs. generic drugs, specialty vs. non-specialty drugs, and drugs from important therapeutic categories or for common chronic conditions. Specialty drug classification will be determined using the Wisconsin Medicaid specialty pharmacy drug classification, and a sensitivity analysis will be conducted using the Medicare Part D classification for a specialty drug.

Data

We will use enrollment and drug claims data for SeniorCare and Medicare to measure and assess the outcomes. These data contain detailed information on all drugs obtained by enrollees, including drug name, type (e.g., brand vs generic), therapeutic class, and source of payment.

Statistical Analysis

Descriptive statistics will be used to identify trends in the outcomes and comparisons will be made between the SeniorCare (treatment group) and Medicare Part D (control group) programs. We will include both graphical analyses and tabulations. Time-series models will be used to longitudinally assess and compare drug utilization and expenditures between the two programs over time. These models will control for important demographic, socioeconomic, and health status characteristics, as well as seasonal variations in the outcomes and autocorrelation. Propensity score matching may be used to select the most comparable subgroup of Part D enrollees to the SeniorCare population.

Q1-3: How does the prevalence of financial hardship among SeniorCare members compare to similar populations of older adults?

The Wisconsin SeniorCare drug assistance program was implemented on September 1, 2002 with the goal to make prescription drugs more affordable to Wisconsin seniors. SeniorCare offers a prescription drug insurance benefit with affordable and predictable cost sharing, which is proposed to reduce the out-of-pocket costs and financial hardship seniors experience in affording their medications. Thus, assessing financial hardship is important to evaluate whether the program is helping low-income older adults to afford their medications. This is particularly relevant given that similar populations of older adults in the Medicare Part D program experience significant levels of financial burden due to the high levels of variability in cost sharing for medications.[9]

Outcomes

This outcome will be assessed by adapting claims-based measures of financial burden used in the literature. For example, the ratio of total annual out-of-pocket costs for drugs to annual household income will be calculated, and the threshold of greater than 5% (or 10%) will be used to define having high financial burden for drugs.[10]

Data

Enrollment and claims data for SeniorCare and Medicare will be used to obtain annual household income and out-of-pocket spending on drugs.

Statistical Analysis

Descriptive statistics will be used to identify trends in the outcomes and comparisons will be made between the SeniorCare (treatment group) and Medicare Part D (control group) programs. We will include both graphical analyses and tabulations. Time-series models will be used to longitudinally assess and compare the prevalence of financial hardship in affording medications between the two programs over time. These models will control for important demographic, socioeconomic, and health status characteristics. Propensity score matching may be used to select the most comparable subgroup of Part D enrollees to the SeniorCare population.

[9] See, for example: Doshi JA, Li P, Pettit AR, Dougherty JS, Flint A, Ladage VP.2017. Reducing out-of-pocket cost barriers to specialty drug use under Medicare Part D: addressing the problem of "too much too soon". Am J Manag Care. 23(3 Suppl):S39-S45.

[10] Walid FG et al. 2012. The Financial Burden From Prescription Drugs Has Declined Recently For The Nonelderly, Although It's Still High For Many. Health Aff (Millwood).31(2): 408–416.

Hypothesis 2: SeniorCare will have a positive effect on the health outcomes of Wisconsin seniors

Q2-1: How does the quality of medication use (i.e., medication safety, adherence and appropriate use) in SeniorCare compare to older adults enrolled in Medicare Part D?

High quality medication use is believed to lead to positive health outcomes. In order to assess the quality of medication use in the SeniorCare program, we will apply a variety of commonly used quality measures endorsed by CMS (e.g., Medicaid Adult Core Set), and other national quality organizations (e.g., National Quality Forum, or NQF, Pharmacy Quality Alliance, or PQA, National Committee for Quality Assurance, or NCQA).[11] These organizations work in partnership with CMS to develop medication use measures and measures for Medicare Part D star ratings.[12] This analysis builds on Hypothesis 1, by providing more specific analyses of drug utilization for certain therapeutic classes or chronic conditions among members in the SeniorCare program. To better understand the quality of medication use in the SeniorCare program, we will utilize a comparison group of older adults with Medicare Part D.

Outcomes

We will apply a wide range of validated, commonly used quality measures in order to provide a comprehensive evaluation of the quality of medication use in the SeniorCare program. This will allow for direct comparisons with existing estimates in the literature. Example measures include but are not limited to: adherence to statins, renin angiotensin system antagonists, and diabetes all class (NQF #0541); Statin use in persons with diabetes (NQF #2712); use of high-risk medications in the elderly (PQA HRM-2017); use of benzodiazepine sedative hypnotic medications in the elderly (PQA BSH); polypharmacy: use of multiple anticholinergic medications in older adults (PQA POLY-ACH); polypharmacy: use of multiple CNS-active medications in older adults (PQA POLY-CNS); concurrent use of opioids and benzodiazepines (NQF #3389); use of opioids at high dosage in persons without cancer (NQF #2940); use of opioids from multiple providers in persons without cancer (NQF #2950); and use of opioids at high dosage and from multiple providers in persons without cancer (NQF #2951).

Data

We will use enrollment and claims data from the SeniorCare and Medicare Part D programs to define the sample for each measure and evaluate the quality of medication use. The technical specifications for each measure will be obtained from the appropriate agencies (e.g., PQA performance measures and value sets) and used or adapted to current best practices in quality measurement.

[11] 2019 Adult Core Set available here: https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2019-adult-core-set.pdf
PQA adherence measures available here: www.pqaalliance.org/adherence-measures.

[12] Available at https://www.pqaalliance.org/assets/Measures/2019_PQA_Measure_Overview.pdf

Statistical Analysis

Descriptive statistics will be used to present trends in the outcomes and will be compared across the SeniorCare and Part D groups. Time-series analysis will be used to assess changes in the level and slope of the outcomes over time between the two groups. The sample will be identified for each quality measure individually by following the inclusion and exclusion criteria defined for each measure. For example, some of the quality measures focus on patients who have specific chronic conditions or use certain types of medications; therefore, such measures will be evaluated amongst the appropriate subgroups of treatment and control group members.

Q2-2: How does the health status of SeniorCare members compare to older adults enrolled in Medicare Part D?

It is believed that by making medications more affordable for Wisconsin seniors, the SeniorCare program will keep members healthier longer. Therefore, it is important to understand the health status of the SeniorCare population and how it changes over time. Given the possibility of self-selection into the SeniorCare and Medicare Part D programs, it is important to understand the different populations covered by the two programs and how they compare on health status.

Outcomes

Claims-based measures of health status will be used to assess changes in health status. This may include the number of type of chronic health conditions, as well as the use of validated measures such as the Charlson Comorbidity Index,[13] Elixhauser Index,[14] or Rx-Risk Comorbidity Index.[15] These indices are widely used to measure comorbidities affecting health status and predict mortality. Using claims-based measures is an efficient way of measuring health status for large populations such as SeniorCare and Medicare Part D enrollees. We will also evaluate if there are any differences in health outcomes attributable to length of time enrolled in SeniorCare.

Data

The analysis will utilize enrollment and claims data for SeniorCare and Medicare.

Statistical Analysis

Descriptive analyses will be used for all outcomes and will be compared between the SeniorCare and Part D groups. Time-series regression analysis will be used to assess changes in the level and slope of the outcomes over time between the groups.

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[13] Charlson ME, Pompei P, Ales KL, MacKenzie CR. 1987. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 40(5):373-83.

[14] Elixhauser A, Steiner C, Harris DR, Coffey RM. 1998. Comorbidity measures for use with administrative data. Med Care 36(1):8-27.

[15] Pratt L, et al. The validity of the Rx-Risk Comorbidity Index using medicines mapped to the Anatomical Therapeutic Chemical (ATC) Classification System (https://bmjopen.bmj.com/content/8/4/e021122)

Q2-3: How do annual trends in health care services utilization and expenditures in the SeniorCare population compare to older adults enrolled in Medicare Part D?

The Wisconsin SeniorCare drug assistance program was implemented on September 1, 2002 and in 2006 Medicare Part D expanded the coverage options available to seniors. SeniorCare is considered creditable coverage, which means it is considered to be as good as the standard Medicare Part D plan. However, it is unknown how SeniorCare enrollment impacts an individual's use of health services, or how SeniorCare members compare to individuals enrolled in Medicare Part D on important domains such as health services use and costs. Medicare is the primary source of health insurance coverage for older adults in the United States, including SeniorCare members. Thus, it is important to assess the impact of SeniorCare coverage on the Medicare program. In addition, comparing these outcomes to a comparable group of older adults in the Medicare Part D program can help us better understand the role that SeniorCare plays in supporting the health of its members.

Outcomes

We will link SeniorCare and Medicare enrollment and claims data to assess the use and costs of health care services for SeniorCare members. Longitudinal analyses will allow us to identify changes in the outcomes over time. Utilization and costs will be assessed for health care services such as inpatient, outpatient, and emergency department visits. In addition, we will estimate the cumulative probability of remaining outside the hospital, as well as the likelihood of hospital admission or emergency department use to identify differences between SeniorCare members and Medicare Part D enrollees.

Data

We will use SeniorCare enrollment and claims data, as well as Medicare enrollment, inpatient, and outpatient claims data to measure the outcomes for SeniorCare members. Medicare enrollment, inpatient, and outpatient claims data will be used to measure the outcomes for the comparison group composed of older adults enrolled in Medicare Part D.

Statistical Analysis

Descriptive analyses will be conducted to describe population-level measures of health services use among SeniorCare members and compare them with a group of older adults in the Medicare Part D population never enrolled in SeniorCare. Time-series regression analysis will be used to assess changes in the level and slope of the outcomes over time between the groups. Propensity score-based weighting may be used to identify an appropriate comparison group to the SeniorCare population and reduce bias due to confounding variables.

Q2-4: What are annual trends in Comprehensive Medication Review and Assessment (CMR/A) utilization and expenditures in SeniorCare?

Comprehensive Medication Review and Assessment (CMR/A) is a type of MTM service, which includes private consultations between a SeniorCare member and a pharmacist to discuss and review that

member's entire medication regimen. These consultations may include a variety of consultative, analytical, and educational services, with the goal of preventing complications, increasing adherence, and controlling costs. It also allows a patient to take more initiative in health management and facilitates partnership between a patient, pharmacist, and physician. SeniorCare members who meet the eligibility criteria may receive CMR/A services from a participating pharmacy provider; similarly, eligible older adults in the Medicare Part D program may also receive these services. Analyzing and comparing trends in the use of CMR/As and the associated expenditures will improve our understanding of how the program has performed over time, and can inform policies and programs promoting the use of these services.

Outcomes

Utilization will be measured using the annual numbers of CMR/A claims and members who received a CMR/A. Expenditures will be evaluated overall and on a per-member basis by source of payment, including total costs, SeniorCare program costs, and member out-of-pocket costs.

Data

We will use SeniorCare enrollment, prescription drug, and MTM data for SeniorCare enrollees.

Statistical Analysis

Descriptive statistics will be used to identify annual trends in the outcomes. Statistical tests (e.g., chi-squared tests, t-tests, ANOVA, and ANCOVA) will be used to assess changes in the outcomes over time.

Q2-5: Are there changes in adherence with recommended vaccine schedules among SeniorCare members after the initiation of SeniorCare vaccination coverage?

SeniorCare will cover vaccinations recommended to older adults by the Centers for Disease Control and Prevention, beginning January 2021 or following approval and implementation of the benefit. Two different categories of vaccine are recommended: 1) vaccines for all older adults aged 65 years or more, and 2) vaccines for older adults with medical conditions or other indications.[16] The first category includes influenza, pneumococcal, diphtheria, tetanus, pertussis, and shingles vaccines. The second category includes meningococcal, hepatitis A and B, and varicella zoster (chicken pox) vaccines. SeniorCare may pay the entire costs for a vaccination if the member has met their required deductible and spenddown, or the remaining part of the costs if a member had other insurance sources that paid some amount of the costs.

The evaluation will assess the role of SeniorCare in supporting older adult's vaccination rates, through analysis and comparison of trends in the vaccine utilization. Wisconsin Immunization Registry (WIR) data will be used to identify vaccine utilization outside the SeniorCare program in order to obtain a complete

[16] U.S. CDC. Recommended Adult Immunization Schedule for ages 19 years or older. United States 2020. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf?fbclid=IwAR3CgLKmaTUNPFTWXVCWZRDxxFGULVT-CSg51lWptMZxgU08M6TVLPwgVok

picture of vaccine use among SeniorCare members, and to determine whether SeniorCare coverage of vaccines acts as a replacement or supplement to other sources of vaccination coverage (e.g. Medicare). If feasible, vaccine utilization among SeniorCare members will be compared with older adults in the Medicaid EBD population that were never enrolled in SeniorCare.

Outcomes
Annual vaccination rates and vaccine expenditures within SeniorCare will be evaluated overall and on a per-member basis, including total costs, SeniorCare program costs, and member out-of-pocket costs.

Data
We will use SeniorCare enrollment and vaccination claims for SeniorCare enrollees. We will also use WIR data to identify vaccine utilization outside the SeniorCare program in order to obtain a complete picture of vaccine use among SeniorCare members.

Statistical Analysis
Descriptive statistics will be used to identify changes in the outcomes, before and after the vaccination coverage. Statistical tests (e.g., chi- squared tests, t-tests, ANOVA, and ANCOVA) will be used to assess changes in the outcomes.

Hypothesis 3: SeniorCare will reduce the likelihood of Medicaid entry and provide cost savings to the Wisconsin Medicaid program.

Question 3-1: How does SeniorCare enrollment impact an individual's likelihood of Medicaid entry?

SeniorCare could produce cost savings to the Medicaid program if, by providing access to medications that help control and prevent adverse health conditions, it reduces the likelihood of Medicaid entry. In addition, SeniorCare can help maintain better health status, which will save Medicaid costs after a member transitions to Medicaid. To evaluate these questions, we will compare the incidence of Medicaid entry between SeniorCare and Medicare Part D populations.

Outcomes
We will assess the rate of Medicaid entry among SeniorCare and Medicare Part D populations and compare the rates between the two groups.

Data
Eligibility and enrollment data for SeniorCare, Medicare, and Medicaid will be used to identify an individual's entry into Medicaid.

Statistical Analysis

Descriptive analyses and statistical comparisons will be conducted to compare the incidence of Medicaid entry among the SeniorCare and Medicare Part D populations. Regression models such as Cox proportional hazard or competing risks model will be used to control for potential confounding factors.

Question 3-2: How does SeniorCare enrollment impact an individual's use of Medicaid-funded nursing home care?

Medicaid is the largest payer for nursing home care in the United States.[17] It is believed that SeniorCare will reduce the need for Medicaid-funded nursing home care among older adults, thus reducing Medicaid costs for these services. To evaluate this assumption, we will identify SeniorCare members who receive Medicaid-funded nursing home care and assess the utilization and costs of this care, which will be compared to other older adults in the Medicaid EBD population that were never enrolled in SeniorCare (e.g., that were enrolled in Medicare Part D). We will also compare the cumulative probability of remaining outside a nursing home between these two groups.

Outcomes

We will link SeniorCare, Medicare, and Medicaid enrollment and claims data to longitudinally assess the health status, utilization of nursing home care, and costs for SeniorCare and Medicare Part D members before and after first entry into the Medicaid EBD population. This will allow for pre-post comparisons to identify changes in the outcomes over time, as well as comparisons between the two groups. In addition, we will estimate the likelihood of transitioning to a nursing home, the cumulative probability of remaining outside a nursing home, and associated factors to identify differences between SeniorCare members and other older adult Medicaid EBD enrollees.

Data

SeniorCare enrollment data will be used to identify former SeniorCare enrollees, and Medicare enrollment data will be used to identify former Medicare Part D enrollees. Medicaid enrollment and nursing home data will be used to identify individuals that transitioned to the Medicaid EBD population and assess the outcomes. Due to the potential for churning in Medicaid programs, our analysis will utilize Medicaid data after an individual's first transition to Medicaid.

Statistical Analysis

Descriptive analyses will be conducted to describe population-level measures of nursing home care among former SeniorCare members in the Medicaid EBD population and a comparison group of older adults in the Medicaid EBD population never enrolled in SeniorCare (e.g., Medicare Part D). Outcomes include the proportion of patients with nursing home use and mean length of stay. Additional outcomes

[17] Kaiser Family Foundation. 2017. "Medicaid's Role in Nursing Home Care." Kaiser Family Foundation Infographic. Issued June 20, 2017. www.kff.org/infographic/medicaids-role-in-nursing-home-care/

based on the existing Medicaid literature[18] will be used to describe nursing home care, including the monthly proportion of individuals residing in nursing homes and the cumulative probability of remaining outside a nursing home. In addition, the likelihood of transitioning to a nursing home will be assessed using time-to-event models for SeniorCare and non-SeniorCare enrollees. Appropriate model choices could include discrete time hazard models and/or Cox proportional hazard models.

Question 3-3: What would Medicaid expenditures be in the absence of the SeniorCare program?

It is believed that SeniorCare will save the Wisconsin Medicaid program money by reducing the likelihood of Medicaid entry, keeping members healthier longer, and mitigating costs related to receiving Medicaid benefits. Thus, it is important to understand how changes to the SeniorCare program might impact Medicaid expenditures. Therefore, we will use cost modeling to estimate how changes to the SeniorCare program might impact Medicaid expenditures.

Outcomes

The main outcome of interest is Medicaid expenditures for SeniorCare members in the absence of the SeniorCare program. We will measure health care expenditures at the annual level (i.e., summing reimbursements for all services received within 12 months). Additional secondary outcomes (e.g., expenditures by service type) will be assessed to identify specific factors contributing to Medicaid expenditures.

Data

SeniorCare enrollment and claims data will be used to identify current patterns in the utilization of prescription drugs among SeniorCare enrollees, and Medicare enrollment and claims data will be used to identify the use of other health services. Medicaid claims data will be used to obtain Medicaid payment amounts for these services, which will be used to project the estimated Medicaid costs for SeniorCare members.

Statistical Analysis

First, current patterns of health services use will be identified for SeniorCare members, as well as the likelihood of Medicaid entry. Next, Medicaid payment amounts for these services will be applied. We will identify Medicaid costs using GLMs with clustered standard errors to determine the Medicaid expenditures in the absence of SeniorCare. From these models we will calculate the predicted reimbursement with the marginal standardization form of predictive margins. For all models, we will adjust for demographics and comorbidity. Additionally, we will include fixed effects for the metropolitan statistical area and services used, which directly adjusts for regional differences in reimbursement and service use mix. We will combine the predicted values for health service use and spending to generate the differences in Medicaid expenditures in the absence of the SeniorCare program. We will use

[18] For example, see Soumerai SB, Ross-Degnan D, Avorn J, McLaughlin TJ, Choodnovskiy I. 1991. Effects of Medicaid drug-payment limits on admission to hospitals and nursing homes." New England Journal of Medicine 325(15):1072-7.

bootstrapping across these models to generate the standard errors and confidence intervals. The sensitivity of the estimates will be tested using alternative model specifications, such as varying the model assumptions (i.e., a hurdle model) and parameters.

V. METHODOLOGICAL LIMITATIONS

The evaluation will use numerous data elements from a variety of sources, each with its own strengths and weaknesses. By working across and combining data sources, we can get a comprehensive look at the SeniorCare population and comparable older adult populations. However, there are important methodological limitations that should be taken into consideration and may have an impact on the evaluation findings.

First, linking different data sources may lead to multiple limitations. When working across multiple data sources, caution should be used when making direct comparisons between the data elements contained in these files. For example, variables may be collected or stored differently, even when the data appear to contain similar elements (e.g., actual vs imputed costs, age as of January 1 vs December 31, etc.). Each data element used in the evaluation will be screened for potential issues of completeness, accuracy, and comparability across data sources, and identical data elements will be used whenever possible to strengthen confidence in the findings. In addition, all data elements will be screened for potential issues with missing or invalid data, and appropriate action will be taken to maximize the utility of the data (e.g., imputation, listwise deletion, etc.).

Identifying individuals across multiple data sources may also prove a challenge, and complete data on individuals may not be available. In particular, data for the Medicare managed care population will be unavailable, as these data are not centrally available through the CMS CCW data warehouse. Similarly, if it is not feasible to accurately identify SeniorCare members in the WIR data, information on immunizations among SeniorCare members, using only the Medicaid/SeniorCare claims data, may be incomplete. In addition, if it is not feasible to identify the Medicaid EBD population in the WIR data, we will not be able to make comparisons of vaccine utilization among SeniorCare members and older adults in Medicaid EBD. However, common IDs are available to link internal data sources such as SeniorCare and Medicaid data, and these data can also be linked to external sources (i.e., Medicare CCW data and WIR data) using a personal identifier such as Social Security numbers. CMS protocols and best practices in data security and privacy will be used to perform these linkages in a secure, HIPAA-compliant manner. Due to the identifiable nature of these data, a data management plan will be developed and approved by CMS and the UW-Madison Institutional Review Board (IRB) that will outline the administrative, physical and technical safeguards, and incident response preparedness for the data.

The ability to apply the proposed validated quality measures (e.g., PQA measures) will vary depending on data availability and the frequency of such services. For example, our ability to conduct detailed analyses of the quality and impact of SeniorCare CMR/A claims may be limited by the small number of such services provided to SeniorCare members. When applying the quality measures, our preferred approach will be to follow the technical specifications outlined for each measure, including the appropriate data requirements and associated inclusion and exclusion criteria. However, if sufficient data are not available, the measures may be adapted to allow for their application in a way that is as

closely related to the intent of the measure as possible (e.g., pooling multiple years of data or relaxing inclusion/exclusion criteria).

VI. SPECIAL METHODOLOGICAL CONSIDERATIONS

The current SeniorCare waiver is an extension of a longstanding waiver, and has been operating smoothly without administrative changes, appeals, grievances, or corrective action plans. There have been no state issues with CMS-64 reporting or budget neutrality. The evaluation design incorporates quasi-experimental methods in order to test how the program is meeting its objectives under changing circumstances. However, due to SeniorCare's longstanding operation since 2002, the evaluation design no longer incorporates baseline data from the program's implementation.

The ability to incorporate comparison groups requires access to national Medicare data and analysis of the experience of seniors in other states that lack access to the SeniorCare program. The proposed evaluation design includes plans to use such Medicare data to the degree that it becomes available.

This evaluation design assesses the goals of the SeniorCare program as they correspond to Hypotheses 2-4 as articulated in the waiver document. Hypothesis 1 and Hypothesis 5 in the waiver document address matters pertaining to the larger prescription drug market and Medicare program generally. These hypotheses are secondary to the SeniorCare program and have been deemed outside of the scope of this waiver evaluation project.

Finally, the SeniorCare waiver was approved for a ten-year operational period. This evaluation plan addresses the first five years of operation, expecting that the hypotheses may be answered within that period and reassessed. At the five-year point, the state may then identify new questions and hypotheses based on the evaluation findings and changes in the environment or other circumstances. This offers a continuous quality improvement approach and learning cycle for the SeniorCare program, as it moves into a mature ongoing operations period.

VII. ATTACHMENTS

A. Waiver approval letter, waiver provisions, and Special Terms and Conditions (STCs)

B. Independent Evaluator Assurance and "No Conflict of Interest" Statement

C. Evaluation Budget

D. Timeline and Major Evaluation Milestones

ATTACHMENT A.
Waiver approval letter, waiver provisions, and Special Terms and Conditions (STCs)

ATTACHMENT B.
Independent Evaluator: Assurance and "No Conflict of Interest" Statement

The Wisconsin Department of Health Services assures that the independent evaluator, the University of Wisconsin Institute for Research on Poverty and its subcontracting investigators, will conduct a fair and impartial evaluation, prepare an objective and robust evaluation report, and there will be no conflict of interest.

The selected independent evaluator has a record of providing high-quality, independent evaluations for multiple organizations across Wisconsin. The independent evaluator also conducted the independent evaluation of the previous 1115 waiver approved in 2008, 2012, and 2014, the 2016-18 SeniorCare waiver, and numerous other Medicaid initiatives in Wisconsin.

The independent evaluator was screened to assure independence and freedom from conflict of interest. A series of interviews with the independent evaluator revealed that the entity has no conflicts of interest or preconceived notions about what they might find in terms of outcomes related to the new waiver provisions for SeniorCare. The state assures that the independent evaluator will be able to conduct the evaluation freely and without interference from the state or other outside parties connected to the state.

The state encourages the independent evaluator to address any potential conflict of interest in an open and honest manner at any stage of the evaluation process at which it may arise so that it does not diminish its capacity for impartiality and undermine the evaluation outcome. The state also encourages the independent evaluator to report on any pressures or interferences encountered during the evaluation process that did affect, or could have affected, the evaluator's independence or objectivity. The state is committed to fostering transparency throughout the evaluation process by ensuring that necessary data is easily accessible to the independent evaluator.

Any conflicts of interest that may arise during the evaluation process will be required to be disclosed in the evaluation report. In reviewing draft evaluation reports, the state and independent evaluator will agree to follow procedures designed to improve the probability of organizational independence and protection from interference.

Confirmation Statement:
The evaluator, the University of Wisconsin Institute for Research on Poverty, submits this evaluation design report under its institutional letterhead and, in doing so, confirms no conflict of interest in serving as an independent evaluator on this project.

ATTACHMENT C.
Five-Year Evaluation - Consolidated Summary Budget

UW-Employed Staff	Role	Year 01	Year 02	Year 03	Year 04	Year 05	Total
K. Look	Principal Investigator	$ 29,920	$ 33,154	$ 33,941	$ 34,745	$ 35,569	$ 167,328
NH Kim	Research Scientist	$ 97,104	$ 99,774	$ 102,141	$ 104,563	$ 107,041	$ 510,623
D. Friedsam	Project Manager & Researcher	$ 8,055	$ 8,216	$ 8,380	$ 8,548	$ 8,719	$ 41,916
K. Voskuil	Programmer and Data Steward	$ 51,000	$ 52,403	$ 53,646	$ 54,918	$ 56,219	$ 268,184
various	Project Management/Admin Svs	$ 10,608	$ 10,900	$ 11,158	$ 11,423	$ 11,694	$ 55,782
Total UW Staff Costs		**$ 196,687**	**$ 204,446**	**$ 209,266**	**$ 214,196**	**$ 219,240**	**$ 1,043,835**
Office S&E							
Printing and Duplicating		$ 600	$ 600	$ 600	$ 600	$ 600	$ 3,000
Supplies		$ 600	$ 600	$ 600	$ 600	$ 600	$ 3,000
Computer Equipment		$ 2,000	$ -	$ -	$ -	$ -	$ 2,000
Telephone and Internet connection		$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 6,000
Total Office S&E		**$ 4,400**	**$ 2,400**	**$ 2,400**	**$ 2,400**	**$ 2,400**	**$ 14,000**
			$ -	$ -	$ -	$ -	
Travel - Research and Project Meetings		**$ 2,000**	**$ 2,000**	**$ 2,000**	**$ 2,000**	**$ 2,000**	**$ 10,000**
Other Costs							
Dr. A. Winn, Medical College of Wisconsin		$ 6,000	$ 6,000	$ 6,000	$ 6,250	$ 6,250	$ 30,500
Data Purchasing and Data Management Costs**		$ 70,000	$ 80,000	$ 80,000	$ 30,000	$ 30,000	$ 290,000
Total Other Costs		**$ 76,000**	**$ 86,000**	**$ 86,000**	**$ 36,250**	**$ 36,250**	**$ 320,500**
Total Direct Costs		**$ 279,087**	**$ 294,846**	**$ 299,666**	**$ 254,846**	**$ 259,890**	**$ 1,388,335**
Indirect Costs @15%		$ 41,863	$ 44,227	$ 44,950	$ 38,227	$ 38,984	**$ 208,250**
Total Budget, Years 01-05		**$ 320,950**	**$ 339,073**	**$ 344,616**	**$ 293,073**	**$ 298,874**	**$ 1,596,585**

ATTACHMENT D. Timeline of Evaluation Milestones

	Q1-2 2020	Q3-4 2020	Q1-2 2021	Q3-4 2021	Q1-2 2022	Q3-4 2022	Q1-2 2023	Q3-4 2023	Q1-2 2024	Q3-4 2024
Project Start-Up										
Attain needed BAA and DUA										
Secure IRB certification										
Attain sub-agreements with collaborating investigators										
Administrative Data Analysis										
Attain SeniorCare, MCBS, PQA and other specified data										
Clean data and match data files										
Construct analytic files with treatment and comparison groups for each hypothesis and resesarch question										
Begin process of Medicare data acquisition. '										
Refresh data at six month intervals										
Identify and construct relevant outcome measures										
Conduct analyses - for interim and final reporting										
Reports										
Evaluation Design Report Updates Finalized										
Interim Annual Reports										
Draft Final Report										
Submit Final Report										

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